

## REMARKS

Claims 1, 2, 5, 8, 17 and 18 were pending as of the Office Action mailed January 4, 2011. Claim 1 has been amended. Support for the amendment to claim 1 may be found within the Applicant's specification at least in claims 1 and 6 as originally filed

Applicant submits that this amendment does not introduce any new matter and is fully supported by the application as filed. Accordingly, entry and consideration of this amendment is respectfully requested.

### **1. Rejection Based on 35 U.S.C. § 112**

The Examiner rejects claims 1, 2, 5, 8, 17 and 18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner alleges that claim 1 is confusing regarding the elements a) through e) following the term "comprising." The Examiner contends that claim 1 reads as the dose of fish oil comprising elements a) through e), and also reads as the flavored capsule comprising elements a) through e).

In response, Applicant has amended claim 1 to clarify that it is the flavored capsule that comprises a) through d). Element e), "a dose of fish oil," has been deleted to clarify that the flavored capsule itself does not comprise a dose of fish oil. Rather, as recited in claim 1, the "dose of fish oil is encapsulated by the flavored capsule." Accordingly, Applicant respectfully requests the withdrawal of this rejection.

### **2. Rejection Based on 35 U.S.C. 103(a)**

Claims 1, 2, 5, 8, 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley, J.P., "Soft Gelatin Capsules" in *The Theory and Practice of Industrial Pharmacy*, pg. 398-412, (Leon Lachman, Herbert A. Lieberman & Joseph L. Kanig, eds., 3rd Edition, 1986)(herein, "Stanley"); in view of Hutchinson *et al.*, U.S. Patent No. 5,817,323 (herein, "Hutchinson"). The Examiner alleges that it would have been obvious at the time of invention to provide a gelatin capsule to deliver fish oil comprising a shell containing gelatin, plasticizer, up to 5% water soluble sucrose and/or up to 2% of essential oil flavor and 6-10% water as taught by

Stanley and to replace the sucrose and/or the essential oil in the shell with the lemon flavor as taught by Hutchinson. *See* Office Action at 5-6.

The Examiner further asserts that the objective evidence presented in several declarations filed with Applicant's Office Action response filed August 18, 2010 (the "August 2010 Office Action response") is insufficient to overcome the § 103(a) over the cited references. Specifically, the Examiner alleges that there was no showing that the objective evidence of unexpected results, long felt need and commercial success was commensurate in scope with the instant claims. *See* Office Action at 8.

Applicant respectfully disagrees that the amended claims are *prima facie* obvious over the cited references. Further, Applicant respectfully submits that previous evidence of secondary consideration presented in the August 2010 Office Action response is commensurate in scope with the claimed subject matter and that this previous evidence is sufficient to rebut any possible conclusion of obviousness over the cited references.

#### **2.1.1. Previous Evidence of Secondary Consideration is Almost Exactly Within the Scope of the Amended Claims**

Applicant respectfully submits that evidence of secondary considerations previously presented in Applicant's August 2010 Office Action response is almost exactly commensurate in scope with the amended claims. The Examiner asserts that the evidence of nonobviousness and commercial success previously presented by Applicant in the August 2010 Office Action response is not commensurate in scope with the claims of the instant application. The Examiner contends that claims 1, 2, 5, 8, 17, 18 encompass "any ingredients and doses of the content of the capsule other than fish oil and flavor." *See* Office Action at 9. The Examiner also asserts that it is not demonstrated whether the evidence of success of the flavored gelatin capsule fish oil supplements presented is due to the flavor in the capsule itself; such success could be due to flavor contained with the dose of fish oil. *See* Office Action at 9-10. Thus, the Examiner concludes that the evidence of secondary consideration presented in Applicant's August 2010 Office Action response is not commensurate in scope with the claims of the instant application. Applicant respectfully disagrees with the Examiner's assertions.

Applicant respectfully submits that the evidence of secondary consideration presented in the August 2010 Office Action is commensurate in scope with the claims of the instant application. Applicant respectfully submits that claims 1, 2, 5, 8, 17, 18 do not encompass "any

ingredients and doses of the content of the capsule other than fish oil and flavor” as alleged by the Examiner. As amended, claim 1 recites, “[a] flavored capsule encapsulating a dose of fish oil, comprising a flavored capsule and a dose of fish oil, wherein the flavored capsule comprises: a) a forming agent chosen from the group consisting of gelatin and vegetable starch; b) a capsule softener; c) water; and d) a water soluble flavoring; wherein said capsule softener is present in the range of about 10% to about 35%, the water is present in the range of about 6% to about 10%, the water soluble flavoring is present in a concentration of about 1.5%, the water soluble flavoring is a lemon flavor, and wherein the dose of fish oil is encapsulated by the flavored capsule. Thus, the claims as amended do not include “any ingredients and doses of the content of the capsule other than fish oil and flavor.” Rather, the claims are directed to a flavored capsule which encapsulates a dose of fish oil.

Applicants submit that the products described in the previously submitted declarations fall within the scope of the claims as amended. For example, it is noted that the flavored gelatin capsules referred to in the sales figures in the Declaration of Opheim of September 21, 2006 contain “gelatin, capsule softener present in an amount of approximately 30-32%, water present in an amount of approximately 8% and a water soluble flavoring (typically a lemon flavoring) present in an amount of approximately 1.5%.” *See* Declaration of Opheim of January 16, 2009, ¶ 3. The formulations of fish oil in the Declaration of Cooperman of March 29, 2007 are encapsulated in capsules that contain “gelatin, capsule softener present in an amount of approximately 32%, water present in an amount of approximately 8% and a water soluble flavoring (a lemon flavoring) present in an amount of approximately 1.5%. *Id.* at ¶ 4.

Applicant further submit that the evidence of unexpected results and commercial success provided was due, in part, to a lemon flavored gelatin shell as recited in the instant claims. For example, in the Declaration of Cooperman of March 29, 2007, Declarant notes that increased patient compliance seen with Nordic Naturals’ products is “to a large extent due to flavoring added to [lemon-flavored] shells.” *See* Declaration of Cooperman of March 29, 2007 at ¶ 5, 6. The secondary evidence also demonstrates that Nordic Naturals’ products having lemon flavored gelatin shells sold better than products that did not contain such shells, including unflavored gel capsules, flavored liquids and non-flavored liquids. *See* Declarations of Opheim of September 21, 2006, January 16, 2009, and August 16, 2010. Further, the evidence provided demonstrates that the lemon flavored gelatin shells improved palatability and patient compliance even with

high concentration of fish oils, suggesting that the lemon flavored gelatin shells could improve the palatability of fish oils at lower concentrations as well. *See* Declaration of Cooperman of March 29, 2007.

Thus, since the unexpected results and commercial success provided in the secondary evidence were, in part, due to the lemon flavored gelatin shells and because the evidence encompasses different contents of fish oils, Applicant respectfully submits that the evidence of secondary consideration provided by the aforementioned declarations is almost exactly commensurate in scope with the claims it supports.

#### **2.1.2. Evidence of Secondary Consideration Sufficient Rebut Any Conclusion of Obviousness Over the Cited References**

Applicant respectfully submits that the previous evidence of secondary consideration presented in the aforementioned declarations sufficiently rebut any possible conclusion of obviousness over the cited references. Applicants respectfully submit that this evidence demonstrates unexpected properties and commercial success of the claimed subject matter and that the claimed subject matter satisfies a long felt need.

Applicant contends that the benefits of fish oil as a nutrient have been well known for many years. *See* Declaration of Cooperman of March 29, 2007. However, many of the individuals who could benefit from the nutrient do not take it because of its unpleasant taste and aftertaste. *Id.*; Declaration of Bellizzi of August 16, 2010 at 2, ¶ 7. Applicant contends that the claimed subject matter help to meet the long felt need for a palatable fish oil supplement. *See* Declaration of Cooperman of March 29, 2009. Indeed, substantially improved patient compliance was seen when patients were provided with the claimed subject matter compared to other available fish oil supplements. *See* Declaration of Cooperman of March 29, 2009; Declaration of Opheim of January 16, 2009 at 1-2, ¶ 3. It is believed that this improved patient compliance is due to the flavoring added to the gelatin shell of the supplements. *See* Declaration of Cooperman of March 29, 2009.

Flavored gelatin capsule fish oil supplements, including the claimed subject matter, were initially met with skepticism. *See* Declaration of Bellizzi of August 16, 2010 at 2-3, ¶ 8. When Nordic Naturals, Inc. first attempted to establish its fruit flavored gelatin capsule fish oil supplements, it encountered surprise and disbelief from consumers, retail buyers, sales

representatives and industry professionals alike over the concept of palatable flavored gelatin capsule fish oil supplements. *Id.* The pleasant smell of the flavored gelatin capsules, however, encouraged people to taste the supplements and most found eating the capsules to be a surprisingly pleasant experience. *See Id.* at 2-3, ¶ 5, 6 and 8.

Despite initial skepticism in the industry and with consumers alike, Nordic Naturals flavored gelatin capsule fish oil supplements, including the claimed subject matter, have gained commercial success. From 2003-2006, Nordic Naturals sold approximately twenty five more times the number of units of flavored gelatin capsules fish oil supplements, which include lemon flavored capsules fish oil supplements, compared to unflavored counterpart. *See Declaration of Opheim of September 21, 2006.*

Nordic Natural further relates that their flavored gelatin capsule fish oil supplements, which include lemon flavored capsules fish oil supplements, have seen yearly increases in gross revenue from sales since the introduction of the products in 2003. *See Declaration of Opheim of August 16, 2010 at 2, ¶ 6 and Exhibit A.* In 2003, gross revenue from sales of Nordic Naturals' flavored gelatin capsule fish oil supplements were approximately three fold greater than gross revenue from sales of Nordic Naturals' unflavored counterpart products. *Id.* at 2, ¶ 7. In 2009, gross revenue from sales of Nordic Naturals' flavored gelatin capsule fish oil supplements were approximately nineteen fold greater than gross revenue from sales of Nordic Naturals' unflavored counterpart products. *Id.*

The commercial success of Nordic Naturals' flavored gelatin capsule fish oil supplements is directly derived from the claimed flavored gelatin capsules and is not the result of a substantial increase or shift in advertising, consumption by purchasers normally tied to Nordic Naturals, or other business events extraneous to the merits of the flavored gelatin capsule fish oil products. *See Declaration of Opheim of August 16, 2010 at 2, ¶ 9.* Approximately one third of Nordic Naturals' advertising expenses for its flavored gelatin capsule fish oil products in 2008 and 2009 was directed to providing potential consumers with samples of the capsules. *Id.* Thus, a significant portion of Nordic Naturals' advertising expenses was tied to providing potential consumers with an opportunity to taste the flavored gelatin capsule fish oil products. These opportunities have resulted, in significant part, in the increased sales of the flavored capsule fish oil products discussed above. *Id.*

Thus, for at least these reasons at a minimum, Applicant respectfully submits that evidence of long felt but unresolved needs, unexpected results and commercial success provided herein rebut any conclusion of *prima facie* obviousness over the cited references. Accordingly, Patent Owner respectfully requests the withdrawal of the rejection based on 35 U.S.C. § 103(a).

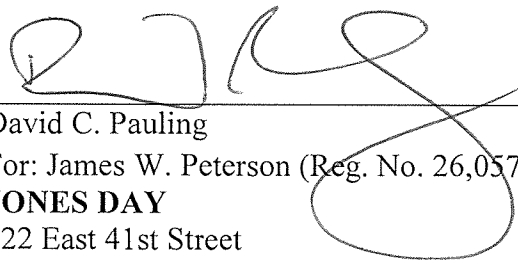
### CONCLUSION

Applicant respectfully requests that the foregoing amendments and remarks be entered and made of record in the file history of the above-identified application.

All rejections are believed to be overcome, and reconsideration of the pending claims is respectfully requested. The Examiner is invited to call the undersigned attorney if a telephone call would help resolve any remaining issues.

Respectfully submitted,

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